IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

IN RE: BEXTRA AND CELEBREX MARKETING SALES PRACTICES AND PRODUCT LIABILITY LITIGATION,

_____/

This order relates to:

All Celebrex Purchase Claims Actions

_____/

No. M: 05-1699 CRB

MEMORANDUM AND ORDER RE: MOTION TO DISMISS PURCHASE CLAIMS MASTER CELEBREX COMPLAINT

These putative class action lawsuits arise out of the marketing and sale of the prescription drug Celebrex. Now pending before the Court is the Pfizer defendants' motion to dismiss. After carefully considering the papers filed by the parties, and having had the benefit of oral argument, as well as further briefing after argument, the Pfizer defendants' motion is DENIED in part and GRANTED in part with leave to amend.

ALLEGATIONS OF THE PURCHASE CLAIMS MASTER CELEBREX COMPLAINT

Non-steroidal anti-inflammatory drugs ("NSAIDs") have been widely used for pain relief for several years. NSAIDs, however, have certain side effects, including gastrointestinal toxicity which results in thousands of deaths every year. Celebrex Master Complaint ("Complaint") ¶¶ 6, 81. Defendants (hereinafter referred to as "Pfizer") developed Celebrex, a NSAID known as a COX-2 inhibitor, with the hope that it would have

fewer gastrointestinal side effects than traditional NSAIDs and thus become a "blockbuster drug with sales in the billions of dollars." Id. ¶¶ 8, 88.

Pfizer aggressively marketed Celebrex to consumers and medical professionals "to create the impression and demand for Celebrex as a wide-ranging pain reliever that would enhance consumers' abilities to live a normal life or engage in activities . . . that many who suffer from chronic pain have difficulty performing." Id. ¶ 13. Plaintiffs allege this marketing scheme was deceptive because Pfizer (1) suppressed data showing the cardiovascular risks associated with the use of Celebrex, see, e.g., id. ¶¶ 13, 170, 193; (2) falsely claimed that the use of Celebrex had fewer gastrointestinal side effects than traditional NSAIDs, see, e.g., id. ¶¶ 13, 92-139; and (3) falsely claimed that Celebrex provided superior pain relief and safety over traditional NSAIDs. See, e.g., id. ¶¶ 13, 174-184. Pfizer's marketing was successful: in 2004 Celebrex achieved $3.3 billion in worldwide sales, 82 percent of which occurred in the United States. That same year Celebrex accounted for 6.3 percent of Pfizer's total worldwide sales. Id. ¶ 14.

As a result of the marketing success, Pfizer was able to sell Celebrex "at a premium price over NSAIDs and to have it become a standard treatment option as opposed to use of less expensive NSAIDs." Id. ¶ 15. "Celebrex sells for $2.53 to $6.45 per day depending upon the dose, while NSAIDs sell for $0.21 to $0 .31 per day." Id. ¶ 17. "If Defendants had not engaged in the wrongful marketing, advertising and promotion of Celebrex, Plaintiffs and Class Members would have paid for other equally effective and less expensive medications." Id.

PROCEDURAL HISTORY

Plaintiffs have filed several putative class actions seeking damages from their purchases of Celebrex as a result of Pfizer's allegedly deceptive scheme. All of the Celebrex purchase claims, as well as the product liability personal injury actions, were transferred to this Court by the Multi-District Litigation Panel. At plaintiffs' request, and over Pfizer's objection, the Court allowed plaintiffs to file a Purchase Claims Master Celebrex Complaint. The Complaint includes four claims for relief: (1) RICO; (2) state consumer protection laws;

(3) unjust enrichment; and (4) breach of warranty. Plaintiffs seek damages on behalf of a national class of all Celebrex "End-Payors located in the United States, including Consumers and Third-Party Payors who purchased and/or paid for Celebrex not for resale during the period from December 1, 1998 through the present." Complaint ¶ 3.

Pfizer moves to dismiss all the claims in the Complaint. Pfizer argues that plaintiffs' claims are preempted because they conflict with the Food, Drug and Cosmetic Act ("FDCA") and the authority of the Food and Drug Administration ("FDA") to regulate warnings about prescription medicine and the promotion of such medicine. Pfizer also alleges that plaintiffs have failed to allege injury in fact and causation. As the Court explained at oral argument, this Memorandum and Order will address preemption only; Pfizer may renew its other arguments in a motion to dismiss an amended complaint.

STANDARD OF REVIEW

When deciding a motion to dismiss the Court must accept plaintiffs' allegations as true and construe them in a light most favorable to the plaintiffs. Parks School of Business v. Symington, 51 F.3d 1480, 1484 (9th Cir. 1995). A district court should not dismiss for failure to state a claim "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of [the plaintiff's] claims which would entitle [the plaintiff] to relief." Barnett v. Centoni, 31 F.3d 813, 816 (9th Cir. 1994) (per curiam). In addition to the allegations of the complaint, the court can consider the actual content of documents referred to in the complaint, as well as documents of which a court may take judicial notice. See Kourtis v. Cameron, 419 F.3d 989, 994 n.2 (9th Cir. 2005).

DISCUSSION

"A fundamental principle of the Constitution is that Congress has the power to preempt state law." Crosby v. National Foreign Trade Council, 530 U.S. 363, 372 (2000). State law is impliedly "preempted to the extent of any conflict with a federal statute." Id. Such preemption applies "where it is impossible for a private party to comply with both state and federal law, and where, 'under the circumstances of [a] particular case, [the challenged state law] stands as an obstacle to the accomplishment and execution of the full purposes and

objectives of Congress.'" Id. (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)); see also Geier v. American Honda Motor Corp., 529 U.S. 861, 873 (2000) (holding that both forms of conflict preemption–conflicts that make it impossible to comply with both state and federal law and conflicts that frustrate the accomplishment of a federal objective–nullify state laws under the Supremacy Clause). Federal regulations have the same preemptive effect as federal statutes. See Fidelity Fed. Sav. and Loan Ass'n v. de la Cuesta, 458 U.S. 141, 158 n.13 (1982). There is a presumption, however, "that state or local regulation of matters related to health and safety is not invalidated under the Supremacy Clause." Hillsborough County, Fla. v. Automated Medical Laboratories, Inc., 471 U.S. 707, 715 (1984).

A. The FDA's regulation of Celebrex

The FDCA requires FDA approval of a prescription drug as "safe and effective" before a manufacturer may sell the drug in the United States. 21 U.S.C. § 393(b)(2)(B). The FDA approved Celebrex as "safe and effective for use as recommended in the submitted labeling" on December 31, 1998. The FDA's approval required Pfizer to market Celebrex in exact accordance with the label approved by the FDA. Complaint ¶ 128; Pfizer Request for Judicial Notice ("RJN"), Exh. 2 at 10.

1. Cardiovascular risk warnings

The original Celebrex label approved by the FDA included a warning for "aggravated hypertension," but did not otherwise warn of cardiovascular risks. RJN, Exh. 3 at 27. In May 1999, the FDA revised the label so that it reported the cardiovascular adverse events of angina pectoris, coronary artery disease, and myocardial infarction occurring in less than two percent of the studied patients, but the label did not otherwise warn of cardiovascular risks. RJN, Exh. 4 at 34. According to plaintiffs, a study completed in 2000 (the CLASS study) and provided to the FDA revealed a tendency in Celebrex patients toward increased cardiovascular toxicity. The FDA nonetheless did not require Pfizer to modify the Celebrex label to include an additional cardiovascular risk warning. Complaint ¶¶ 186-89. Indeed, an FDA Medical Officer who reviewed the CLASS data concluded that the data did not support a large adverse effect of Celebrex on cardiovascular mortality. At the time of the Medical

Officer's review, however, Pfizer had not disclosed to the FDA the results of a June 1999 study that, according to plaintiffs, revealed increased cardiovascular risk. Plaintiffs allege that had Pfizer timely disclosed the June 1999 study, the FDA would have placed more significance on the cardiovascular risks revealed by the CLASS study. Id. ¶¶ 186, 192. Pfizer submitted the results of the June 1999 study to the FDA in 2001. Id. ¶ 200.

In February 2001, an FDA Advisory Panel met to review the cardiovascular risk of Vioxx (another Cox-2 inhibitor) and Celebrex as reflected in a study of Vioxx (the VIGOR study) and the CLASS study. Complaint ¶ 170. As a result of the review, the FDA required the Vioxx label to warn that the VIGOR study showed that "the risk of developing a serious cardiovascular thrombotic event was significantly higher in patients treated with VIOXX . . . as compared to patients treated with naproxen." RJN, Exh. 9 at 72. In contrast to Vioxx, the FDA specifically determined that the CLASS study showed that the overall rate of serious adverse cardiovascular events for patients taking Celebrex was no higher than in patients taking other NSAIDs. RJN, Exh. 10 at 91. Thus, the FDA did not require Pfizer to include a cardiovascular warning as it did with Vioxx. Complaint ¶¶ 96, 200. Indeed, the revised label the FDA required in June 2002 reported that the CLASS study showed that there was no difference in the rate of serious adverse cardiovascular events for Celebrex than for other NSAIDs. RJN, Exh. 11 at 101, Exh. 12 at 106.

Merck withdrew Vioxx from the market because of cardiovascular risks in September 2004. Complaint ¶ 197. In April 2005, the FDA issued a memorandum analyzing COX-2 inhibitors and cardiovascular risk. The FDA concluded that COX-2 drugs, including Celebrex, are associated with an increased risk of serious adverse cardiovascular events compared to a placebo, but that the data do not clearly demonstrate that COX-2 inhibitors pose a greater risk than other NSAIDs. RJN, Exh. 15 at 138. The FDA also concluded that the benefits of Celebrex outweigh the risks in appropriate patients and therefore Celebrex should remain on the market as a prescription drug. Id. at 153. As a result of these findings, the FDA ordered Pfizer to include a "boxed warning" on the Celebrex label that highlights the potential increased risk of serious adverse cardiovascular events. The warning, required as of

August 2005, states: "CELEBREX may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. All NSAIDs may have similar risk. This risk may increase with duration of use. Patients with cardiovascular disease may be at greater risk." RJN, Exh. 16 at 169.

2. Gastrointestinal ("GI") risks warnings

When the FDA approved Celebrex for sale it warned Pfizer that "any promotional activities 'that make or imply comparative claims about the frequency of clinically serious GI events compared to NSAIDs or specific NSAIDs will be considered false and/or misleading . . . .'" Complaint ¶ 90. The FDA required the Celebrex label to include a warning that "serious gastrointestinal toxicity 'can occur at any time, with or without warning symptoms, in patients treated with non-steroidal anti-inflammatory drugs (NSAIDs)." Id. ¶ 91.

In 2005, the FDA required the Celebrex label to include a boxed GI warning as follows: "NASIDs, including CELEBREX, cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal." RJN, Exh. 16 at 169.

B. Plaintiffs' claims

Pfizer moves to dismiss plaintiffs' claims on the ground that they conflict with the FDA's regulation of Celebrex.

1. The cardiovascular risk claims

The Complaint plainly alleges that Pfizer's marketing of Celebrex was unlawful because Pfizer failed to disclose increased cardiovascular risk. See, e.g., Complaint ¶¶ 13, 170, 193. Plaintiffs are asserting, in effect, that Pfizer should have included an additional warning on the Celebrex label and in the Celebrex advertising--a warning not required by the FDA.

In their opposition to Pfizer's motion to dismiss plaintiffs appear to abandon any such claim: "Plaintiffs do not challenge Celebrex's FDA-approved label. Instead, they challenge Pfizer's improper promotion of Celebrex in a manner inconsistent with that label. Nor do

Purchaser Plaintiffs seek to replace the FDA's judgment with their own." Plaintiffs' Opposition at 11. These statements are difficult to reconcile with the allegations of the Complaint. In their briefing after oral argument, however, plaintiffs appear to reverse position again, this time arguing that state laws may require manufacturers to place additional risk information on their labels and in promotional materials. In any event, as plaintiffs have not formally and unequivocally abandoned their cardiovascular risk claims, the Court will decide whether such claims are preempted.

Many courts have held that such "failure to warn" claims do not conflict with FDA regulations and are therefore not preempted. These courts reason that FDA drug labeling requirements impose only "minimum standards" that may be supplemented by state law and therefore the state laws do not conflict with federal law. See, e.g., Peters v. Astrazeneca, LP, 417 F.Supp.2d 1051, 1056 (W.D. Wis. 2006) (no conflict preemption of claim that defendant failed to warn drug could cause damage to the senses); Zikis v. Pfizer Inc., 2005 WL 1126909 *3 (N.D. Ill. May 9, 2005) (no conflict between state law claim seeking additional drug warning and federal law); Eve v. Sandoz Pharmaceutical Corp., 2002 WL 181972 *3 (S.D. Ind. Jan. 28, 2002) (same); Motus v. Pfizer Inc., 127 F.Supp.2d 1085, 1091 (C.D. Cal. 2000) ("[M]ost courts have found that FDA regulations as to design and warning standards are minimum standards which do not preempt state law . . . failure to warn claims"); see also Wells v. Ortho Pharmaceutical Corp., 788 F.2d 741, 746 (11th Cir. 1986) ("An FDA determination that a warning is not necessary may be sufficient for federal regulatory purposes but still not be sufficient for state tort law purposes"). The conclusion that FDA labeling requirements are merely minimum standards is based on the courts' assumption that FDA regulations permit a drug manufacturer to add warnings to its label without prior FDA approval. See, e.g., Eve, 2002 WL 181972 at *3 (citing 21 C.F.R. § 314.70(c)(2)(i) (2002)); Motus, 127 F.Supp.2d at 1093-94 (same).

Other courts, however, have held that a state law claim that challenges a drug company's failure to warn of a particular risk conflicts with federal law and is preempted, at least where the FDA actually considered and rejected a similar warning. See, e.g., Needleman

v. Pfizer Inc., 2004 WL 1773697 *4-5 (N.D. Tex. Aug. 6, 2004); Dusek v. Pfizer Inc., 2004 WL 2191804 *9-10 (S.D. Tex. Feb. 20, 2004); Dowhal v. Smithkline Beecham Consumer Healthcare, 32 Cal.4th 910, 928-29 (2004).

a. The FDA's preemption position

The FDA recently opined on what state laws conflict with its regulation of prescription drugs. In the preamble to a Final Rule regarding "Requirements on Content and Format of Labelling for Human Prescription Drug and Biological Products," the FDA states that it "believes that State laws conflict with and stand as an obstacle to achievement of the full objectives and purposes of Federal law when they purport to compel a firm to include in labeling or advertising a statement that FDA has considered and found scientifically unsubstantiated." 71 Fed. Reg. 3935 (2006). The FDA expressly disagrees with those cases that have held that state-law failure to warn claims are not preempted because "a manufacturer has latitude under FDA regulations to revise labeling by adding or strengthening warning statements without first obtaining permission from FDA." Id. at 3934 (citing cases). "In fact, the determination whether labeling revisions are necessary is, in the end, squarely and solely FDA's under the act." Id. "A manufacturer may, under FDA regulations, strengthen a labeling warning, but in practice manufacturers typically consult with FDA before doing so to avoid implementing labeling charges with which the agency ultimately might disagree (and that therefore might subject the manufacturer to enforcement action)." Id.

The FDA also expressly disagrees with the courts' assumption that FDA labeling requirements represent minimum standards that may be supplemented by state law. "FDA interprets the act to establish both a 'floor' and a 'ceiling,' such that additional disclosures of risk information can expose a manufacturer to liability under the act if the additional statement is unsubstantiated or otherwise false or misleading." Id. at 3935.

> Given the comprehensiveness of FDA regulation of drug safety, effectiveness, and labeling under the act, additional requirements for the disclosures or risk information are not necessarily more protective of patients. Instead, they can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use. Exaggeration of risk could discourage appropriate use of a beneficial drug.

Id.; see also id. ("State law attempts to impose additional warnings can lead to labeling that does not accurately portray a product's risks, thereby potentially discouraging safe and effective use of approved products or encouraging inappropriate use and undermining the objectives of the act"). The FDA adds:

> State law actions also threaten FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs. State actions are not characterized by centralized expert evaluation of drug regulatory issues. Instead, they encourage, and in fact require, lay judges and juries to second-guess the assessment of benefits versus risks of a specific drug to the general public–the central role of the FDA–sometimes on behalf of a single individual or group of individuals. That individualized reevaluation of the benefits and risks of a product can result in relief–including the threat of significant damage awards or penalties–that creates pressure on manufacturers to attempt to add warnings that FDA has neither approved nor found to be scientifically required. This could encourage manufacturers to propose "defensive labeling" to avoid State liability, which, if implemented, could result in scientifically unsubstantiated warnings and underutilization of beneficial treatments.

Id.

b. The Court must give deference to the FDA's view

The FDA's interpretation of the preemptive effect of its regulations is entitled to deference. In Geier, for example, the Supreme Court "gave weight" to the Department of Transportation's view that its airbag regulations preempt certain state laws. The Court held that deference was appropriate because "Congress has delegated to DOT authority to implement the statute; the subject matter is technical; and the relevant history and background are complex and extensive. The agency is likely to have a thorough understanding of its own regulation and its objectives and is 'uniquely qualified' to comprehend the likely impact of state requirements." 529 U.S. at 883.

The same reasoning applies here. Congress has delegated to the FDA authority to implement the FDCA; "the subject matter is technical; and the relevant history and background are complex and extensive." Id. The FDA is thus "likely to have a thorough understanding of its own regulation and its objectives and is 'uniquely qualified' to comprehend the likely impact of state requirements." Id.; see also Medtronic, Inc. v. Lohr, 518 U.S. 470, 506 (1996) (Breyer, J., concurring) (stating that the FDA's responsibility for implementing the Medical Devices Act "means informed agency involvement and, therefore,

special understanding of the likely impact of both state and federal requirements, as well as an understanding of whether (or the extent to which) state requirements may interfere with federal objectives"); Hillsborough County v. Automated Medical Labs., 471 U.S. 707, 714-15 (1984) (holding that the FDA's statement that particular regulations did not preempt state law was "dispositive on the question of implicit intent to pre-empt unless either the agency's position is inconsistent with clearly expressed congressional intent, or subsequent developments reveal a change in that position").

Plaintiffs argue that because the FDA's statement appears in a preamble to a Final Rule, and is not itself a regulation or even an interpretative rule, the Court must ignore the FDA's view. The Supreme Court disagrees. In Hillsborough, the Court found that certain state law claims were not preempted because, among other things, the FDA had never indicated its belief that its regulations preempted state law: "because agencies normally address problems in a detailed manner and can speak through a variety of means, including regulations, *preambles*, interpretative statements, and responses to comments, we can expect that they will make their intentions clear if they intend for their regulations to be exclusive." 471 U.S. at 718 (emphasis added); see also de la Cuesta, 458 U.S. at 158 n.13 (giving deference to an agency's preamble statement on the preemptive effect of its regulations). Indeed, the Court has given weight to an agency's view of preemption as articulated by the Solicitor General in an amicus brief. Geier, 529 U.S. at 883. It follows, then, that the FDA's failure to comply with Executive Order 13132 regarding consultation with local officials about a possible conflict with state law does not mean that this Court cannot consider the FDA's view of how certain state laws stand as an obstacle to the accomplishment of the objectives of Federal law.

Plaintiffs' contention that Congress has not delegated authority to the FDA to opine on the preemptive effect of its regulations is also unavailing. Congress has delegated the responsibility for administering the FDCA to the FDA; such responsibility implies the authority and expertise to determine which state laws conflict with its regulations. See Geier, 529 U.S. at 883; Hillsborough County, 471 U.S. at 721; see also Medronic, Inc., 518 U.S. at

505 (Breyer, J., concurring) (noting that the Supreme Court "has previously suggested that, in the absence of clear congressional command as to pre-emption, courts may infer that the relevant administrative agency possesses a degree of leeway to determine which rules, regulations or other administrative actions will have pre-emptive effect"). Congress's omission of a federal damages remedy in the FDCA is not a "clear congressional command" of no preemption.

Plaintiffs are correct that in determining what weight to give the FDA's preemption view the Court should consider the consistency in the FDA's position. See Geier, 529 U.S. at 883 (noting that the DOT's view on preemption should make a difference because, among other things, the view has been consistent over time); Colacicco v. Apotex, Inc., 432 F.Supp.2d 514, 525 (E.D. Pa. 2006) (stating that in according deference to an agency's view, courts should consider "the consistency with which the agency has applied the particular interpretation"). Plaintiffs highlight FDA statements to the effect that its labeling regulations establish minimum standards, 44 Fed. Reg. 3735 (1979); 63 Fed. Reg. 66384 (1998); indeed, in 2000, when the FDA published the proposed drug labeling rule–the rule to which the preemption preamble is attached–the FDA determined that the proposed labeling rule does not preempt state law. 65 Fed. Reg. 81082 (2000). The following year, after a change in the leadership of the Executive Branch, the FDA began for the first time to submit amicus briefs arguing in favor of preemption. 71 Fed. Reg. 3934; Colacicco, 432 F.Supp.2d at 531-32.

While the FDA's current view of the preemptive effect of its labeling regulations is a 180-degree reversal of its prior position, the Supreme Court has recognized that an agency's view of the preemptive effect of its regulations may change over time as the agency gains more experience with the interrelationship between its regulations and state laws. See Hillsborough, 471 U.S. at 714-15 (noting that an agency's statement of no preemption is dispositive "unless subsequent developments reveal a change in that position"); Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 863-64 (1984) (holding that the fact that the agency had from time to time changed its interpretation of a term does not mean no deference is accorded the agency's current view: "On the contrary, the agency, to engage in informed

rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis"). Moreover, the Supreme Court has never held that a court may not give weight to an agency's view of the preemptive effect of its own regulations simply because that agency's view changed contemporaneously with a change in administration. And, as the Colacicco court notes, the FDA's view has been consistent since 2000. 432 F.Supp.2d at 531-32.

Finally, the FDA's view of the preemptive effect of its own regulations is not "plainly erroneous or inconsistent with the regulation." Auer v. Robbins, 519 U.S. 452, 461 (1997). Its preemption position is premised on its assertion "the determination whether labeling revisions are necessary is, in the end, squarely and solely the FDA's under the act." 71 Fed. Reg. 3934. The FDA explains that while a manufacturer can distribute a unilaterally strengthened label after giving the FDA prior notice, the FDA retains authority to disapprove the label. 71 Fed. Reg. 3934. The FDA's opinion is reasonable: while a manufacturer may distribute a drug with changes to the label to add or strengthen a warning after giving the FDA notice of the change (a "supplemental application"), 21 C.F.R. § 314.70(c)(6)(iii)(A)(2004), the FDA may disapprove of the supplemental application and order the manufacturer to cease distribution of the drug with the changed label. 21 C.F.R. § 314.70(c)(7)(2004). And, even before the FDA adopted the regulation explicitly stating that it could order a manufacturer to cease distribution of a drug after disapproving the supplemental application, it had the authority under the FDCA to pursue an enforcement action against a drug manufacturer. See Heckler v. Chaney, 470 U.S. 821, 835 (1985); 21 U.S.C. § 352; see also Ehlis v. Shire Richwood, Inc., 233 F.Supp.2d 1189, 1198 (D.N.D. 2002) (noting that manufacturers are prohibited from changing the labels for prescription drugs without prior approval from the FDA "except in limited circumstances for a limited amount of time"). The FDA explains further that because of its final authority over the content of prescription drug labels, manufacturers typically consult with the FDA before making a label revision. None of the post-preamble cases cited by plaintiffs address the FDA's final authority over label revisions. See, e.g., Jackson v. Pfizer, Inc., 432 F.Supp.2d 964 (D. Neb. 2006); Laisure-Radke v. Par Pharmaceutical, Inc., 2006 WL 901657 *4-5 (W.D. Wash. March 29, 2006).

Plaintiffs also argue that if any failure to warn claims conflict with federal law, it is only those claims that seek to hold a manufacturer liable for failing to give a warning which the FDA has expressly found to be false and misleading. In Needleman, for example, the plaintiff claimed that Pfizer had failed to adequately warn of the risk of suicide from taking Zoloft, an anti-depressant. The district court found that the "FDA has clearly determined that a warning linking Zoloft and suicide would be false, misleading, and harmful to patients" and therefore the plaintiff's state law claims conflicted with the federal regulation of Zoloft and were preempted. 2004 WL 1773697 at *2, 4-5; see also Dusek, 2004 WL 2191804 at *9 (same).

The FDA's view of preemption may be somewhat broader: "FDA believes that State laws conflict with and stand as an obstacle to achievement of the full objectives and purposes of Federal law when they purport to compel a firm to include in labeling or advertising a statement that FDA has considered and found scientifically unsubstantiated." 71 Fed. Reg. 3935; see also id. at 3936 (stating that "claims that a sponsor breached an obligation to warn by failing to include contraindications or warnings that are not supported by evidence" are preempted). Thus, the FDA's view is that a claim is preempted if the FDA determined that the warning the plaintiff seeks to impose is not supported by the evidence before the FDA; the FDA does not also have to expressly determine that the warning would be false and misleading, although the FDA has suggested that an unsubstantiated statement is "false or misleading." See 71 Fed. Reg. 3935 (stating that additional disclosures of risk information can expose a manufacturer to liability under the act if the additional statement *is unsubstantiated or otherwise false or misleading*") (emphasis added).

The Court cannot conclude that the FDA is wrong; the FDA is the agency charged with administering the FCDA and striking a "somewhat delicate balance" among its statutory objectives. Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 348 (2001). The FDA is in a better position than the Court to determine whether state laws that encourage manufacturers to propose defensive labels upset the FDA's careful balance of statutory objectives.

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c. The cardiovascular risk claims are preempted

The next question, then, is whether plaintiffs seek to hold Pfizer liable for failing to include in its promotional materials a warning which the FDA has determined is not substantiated by scientific evidence. The Complaint is oblique as to what cardiovascular risk warning Pfizer should have given physicians and consumers. It is apparent, however, that plaintiffs contend that even the current warning required by the FDA–that Celebrex, as with all NSAIDs, may cause an increased risk of serious adverse cardiovascular events–is inadequate. See Complaint at ¶ 196 (stating that the "Black Box" warning required as of August 2005 constitutes only "partial" disclosure). Thus, plaintiffs' theory must be that Celebrex has cardiovascular risks greater than other NSAIDs.

Plaintiffs' failure-to-warn claims therefore attempt to require Pfizer to include in its Celebrex promotion a warning which the FDA has considered and found to be scientifically unsubstantiated. This is not a case where the FDA has not considered the risks of which plaintiffs claim the drug manufacturer should have warned; instead, the evidence properly before the Court establishes that the FDA specifically considered whether Celebrex poses a greater risk of adverse cardiovascular events than other NSAIDs. The evidence also demonstrates that the FDA determined that the scientific evidence does not establish that it does. Plaintiffs' state law failure-to-warn-claims conflict with the FDA's determination of the proper warning and pose an obstacle to the full accomplishment of the objectives of the FDCA.

Plaintiffs' allegation that Pfizer withheld material cardiovascular risk data from the FDA does not change the preemption analysis. The law is well established that a claim premised on a drug manufacturer's failure to provide data to the FDA is preempted. Buckman, Co., 531 U.S. at 348. In Buckman, the Supreme Court concluded that such claims "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." Id. at 350. Allowing state law fraud-on-the-FDA claims would "dramatically increase the burden facing" potential drug applicants by causing applicants "to fear that their disclosures to the FDA, although deemed appropriate by the administration, will later be judged insufficient in state court." Id. at 351; see also Dusek, 2004 WL 2191804 at *7

(stating that plaintiffs' claim that the FDA did not have all the relevant scientific information when it determined that a particular warning was not warranted amounts to a "fraud-on-the-agency" claim). In any event, plaintiffs disavow any intent to make such a claim, and, indeed, acknowledge that their allegations that Pfizer withheld material from the FDA are immaterial to the preemption analysis. Plaintiffs' July 14, 2006 Letter Brief at 9.

Accordingly, plaintiffs' claims premised on Pfizer's failure to warn consumers and physicians of cardiovascular risk are dismissed as preempted. The dismissal is with leave to amend, provided plaintiffs in good faith believe they can amend their claims consistent with the Court's order. Of course, even if plaintiffs believe they can so amend, they may choose not to do so. See Plaintiffs' Opposition at 2 (stating that much of plaintiffs' case has "nothing to do with 'cardiovascular risk'").

2. The GI claims

Pfizer also argues that plaintiffs' other theory of liability, that Pfizer falsely claimed that Celebrex had fewer GI complications than other NSAIDs and was more effective, is preempted because it, too, stands as an obstacle to the accomplishment of the objectives of the FDCA. Pfizer emphasizes that the FDA requires drug companies to submit all advertising to the FDA's Division of Drug Marketing, Advertising, and Communications ("DDMAC"). DDMAC reviews the advertisements for compliance with the FDCA and FDA regulations on advertising, 21 U.S.C. § 352(n), and 21 C.F.R. § 202.1(e), and has the authority to require a company to stop running a particular advertisement or to run a corrective promotion. 70 Fed. Reg. 54059 (2005).

Judicially-noticeable evidence establishes that Pfizer has submitted its challenged Celebrex advertisements to DDMAC and, with a few exceptions, the DDMAC did not object to the advertisements. According to Pfizer, the FDA has "necessarily determined" that the unobjected to advertisements are accurate and strike a fair balance between the benefits and risks of Celebrex; therefore, any claim that such advertisements were deceptive conflicts with the FDA's determination to the contrary and are impliedly preempted. Pfizer Motion to Dismiss at 19-20.

Pfizer cites no authority for its assertion that the FDA's silence as to a particular advertisement means that the FDA "necessarily determined" that the advertisement was not deceptive; indeed, there is nothing in the record from which the Court could conclude that the FDA has actually reviewed all of the submitted advertisements, let alone conclude that the FDA's review means that it has definitively determined that the advertisement was not misleading. Accordingly, Pfizer has not met its burden of showing an actual conflict.

The FDA's silence is significant in another respect. As is apparent from the discussion of the failure-to-warn claim, when the FDA believes that its regulations preempt state law it says so. The FDA has been silent with respect to the preemption of lawsuits challenging false claims in prescription drug advertisements. This silence suggests that the FDA does not intend its review of promotional materials to preempt false advertising claims. See Hillsborough, 471 U.S. at 721-22; see also id. at 718 ("because agencies normally address problems in a detailed manner and can speak through a variety of means, including regulations, preambles, interpretative statements, and responses to comments, we can expect that they will make their intentions clear if they intend for their regulations to be exclusive"). While this silence is not dispositive of conflict preemption, see Geier, 529 U.S. at 884, it is additional evidence of no actual conflict.

Pfizer also argues that particular advertisements identified in the Complaint are entirely consistent with the FDA-required label and therefore any claims based on those advertisements are preempted. Plaintiffs do not directly respond to Pfizer's argument as to particular advertisements; instead, they generally assert that they "seek to recover damages they have suffered as a result of Pfizer's improper promotion of Celebrex in a manner inconsistent with its label." Plaintiffs' Opposition at 14. Plaintiffs' claims are premised on their assertion that the challenged advertisements imply that Celebrex is superior to other NSAIDs because it has fewer GI symptoms, a claim which the FDA expressly determined would be false and misleading. See, e.g., Complaint ¶¶ 90, 108.

Pfizer is actually arguing that certain advertisements were not misleading as a matter of law, that is, that the advertisements do not imply GI superiority or greater efficacy than

traditional NSAIDs. The Court declines to make such a determination on the limited record and briefing currently before the Court. For example, plaintiffs contend that a letter Pfizer provided to Healthcare Professionals implied Celebrex GI superiority by describing Celebrex as the leading brand of prescription arthritis medicine and noting that serious GI toxicity can occur with NSAIDs. Complaint ¶ 129. Pfizer claims this advertisement was entirely consistent with the FDA-approved label because the label warned of the GI complications of patients taking NSAIDs. Pfizer's Reply at 10. The Court cannot so conclude, however, without reviewing the letter; it may be that the letter, as written, did in fact imply that Celebrex has GI superiority, and, on this motion to dismiss and without the letter in the record, the Court must assume that the letter did impliedly make such a claim.

Finally, Pfizer argues that the FDA, not a court or a jury, should initially decide whether Pfizer's advertisements are misleading because plaintiffs' claims fall within the "primary jurisdiction" of the FDA. The primary jurisdiction doctrine is "applicable to claims properly cognizable in court that contain some issue within the special competence of an administrative agency." Reiter v. Cooper, 507 U.S. 258, 268 (1993). "When there is a basis for judicial action, independent of agency proceedings, courts may route the threshold decision as to certain issues to the agency charged with primary responsibility for governmental supervision or control of the particular industry or activity involved." United States v. Gen. Dynamics Corp., 828 F.2d 1356, 1362 (9th Cir. 1987) (internal quotation marks and citation omitted). Plaintiffs' false advertising claims do not implicate the primary jurisdiction doctrine. The issue is not whether Celebrex has fewer GI complications than other over-counter NSAIDs; the FDA has already determined that it does not. The issue is whether contrary to the FDA's findings, Pfizer nonetheless falsely claimed that Celebrex was superior. Courts and juries frequently decide similar false advertising claims.

CONCLUSION

Plaintiffs' claims that Pfizer's promotion of Celebrex was unlawful because it failed to warn of the drug's cardiovascular risks are preempted because they conflict with the FDA's determination of what warnings are substantiated by the scientific evidence. Accordingly, the

failure-to-warn of cardiovascular risk claims are dismissed with leave to amend. Pfizer has not established that the FDA has determined that all of Pfizer's promotional material strikes a "fair balance" and are not false and misleading. Accordingly, Pfizer's motion to dismiss the false advertising claims on conflict preemption grounds is denied.

IT IS SO ORDERED.

Dated: August 16, 2006

CHARLES R. BREYER
UNITED STATES DISTRICT JUDGE